



Appl. No. : 10/829,573
Confirmation No. : 6731
Applicant : Edward J. Coleman, et al.

Filed : April 22, 2004
Title : IMPLANTABLE CARDIAC
ASSIST DEVICE

TC/A.U. : 3762
Examiner : Jeffrey R. Jastrzab

Docket No. : 021587-9001-02

Customer No. 23510

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P.O. Box 1450
Alexandria, VA 22313-1450

I, Sandy Tabachnick, hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date of my signature.

Sandy Tabachnick
Signature

April 24, 2006
Date of Signature

DECLARATION OF DR. EDWARD COLEMAN, UNDER 37 C.F.R. § 1.132

1. I am cardiothoracic surgeon, a position I have held since July 1990. Prior to that, I was an instructor in surgery and resident in cardiothoracic surgery at the State University of New York at Buffalo School of Medicine.
2. Attached hereto, as Exhibit A, is a copy of my *curriculum vitae*.
3. I am the co-inventor of the claimed subject matter of the above identified patent application. I make this declaration in support of prosecution of the application before the U.S. Patent and Trademark Office.
4. I have read and understood the invention as disclosed in the above identified patent application, including the invention described by the presently pending claims, after amendment in the Amendment and Request for consideration, under 37 C.F.R. § 1.111, to be filed herewith.
5. I have reviewed an Office Action from the U.S. Patent and Trademark Office, mailed April 22, 2005. Claims 2-3 stand rejected under 35 USC § 101 as being directed toward non-statutory subject matter. Claims 1-8 stand rejected as being anticipated under 35 USC § 102(e) as being anticipated by U.S. Patent No. 6,602,182 issued to Milbocker

(hereinafter "Milbocker"). I believe the evidence presented herein below demonstrates the subject matter of the claims, as amended, are not disclosed fully disclosed by the Milbocker reference.

6. The cardiac massage apparatus set forth in claim 1 claims an apparatus where the fluid inflating the chambers to flow in a single direction from the input to the output of the chambers and from the apex of the heart to the base of the heart. As the chambers inflate from the apex to the base, this contraction mimics the natural contraction of the heart.
7. In contrast to the cardiac massage apparatus set forth in claim 1, the Milbocker patent discloses an arrangement where the input and output to the fluid chambers are a single tube in a single location near the apex of the heart, where fluid is actively pumped into, and out of, the chambers in a bi-directional fashion. The Millbocker device is configured such that the fluid output of the inflatable elements follows the same path as the fluid input, such that the flow travels back down the cardiac wall. With this design, the inflation and deflation of the Milbocker device creates pressure on the house that induces back-flow of blood into the ventricles of the heart.
8. With the present invention as set forth in claim 1, the input and output ports are separate from each other (i.e. they are not the same opening). Furthermore, fluid is pumped, and flows, in one direction. The fluid flows from the input port to the output port in a continuous fashion, the chamber array being inflated (and subsequently deflated) from the apex to the base of the heart. This upward-only movement by the chamber array prevents blood from within the heart to back-flow into the ventricles. During diastole, blood fills the ventricles. During systole, the chamber array of the present invention inflates, starting from the apex, and contracts the heart muscle to push blood up through the aorta. With the invention set forth in claim 1, the chamber array provides no downward pull to cause the blood to back-flow into the ventricles in operation of this invention.
9. Claim 8, as amended, recites a cardiac massage apparatus having "elastic Bourdon tubes", a pump that pumps fluid "continuously by the pump means to the input port" (i.e.

in one direction) and a “pressure regulator means” that “intermittently inflates and deflates the chamber”. See claim 8, as amended.

10. Bourdon tubes are well known to those of skill in the art. A Bourdon tube is a curved and partially flattened tube that tends to straighten out in proportion to pressure. The unique feature of this is that the material properties of the Bourdon tube in the non-pressurized state return to the “relaxed” or “non-compressive” state. Therefore, in the present invention, when the Bourdon tube is in a pressurized state from the input of fluid from pump, the tubes contract the heart, and when they are not in a pressurized state, the tubes recoil away from heart, facilitating the refilling of heart passively. Thus fluid is only actively pumped by the pump of the invention in one direction. Once the pump stops, the Bourdon tubes are in a non-pressurized state and recoil from the heart, sending the fluid back through an output tube.
11. In contrast to the cardiac massage apparatus set forth in claim 8, the Milbocker patent discloses an arrangement where fluid is actively pumped into, and out of, the chambers. Milbocker thus teaches the use of a bi-directional pump which is completely different than the Bourdon tube concept. This is of important significance in that in the event of failure of the pump, the tubes must be drained so as not to encumber the natural function of the heart. The solution of Milbocker is to use a subdermal port for draining the pumping unit in the event of failure of the hydraulic pumping capacity of the heart. Milbocker teaches that the port can be accessed through a skin puncture with an array of 15 gauge needles. This again is totally different than our device in which during device failure the Bourdon tube returns to its natural state, which is away from the heart. One experienced in the art can readily see that the Milbocker patent requires that recipients of the Milbocker device are required to travel wherever they go with an assortment of syringes and 15 gauge needles in the event of device failure where as our device that is not necessary.
12. In summary, for reasons provided in paragraphs 1-11 above, I believe that the Milbocker patent fails to disclose all of the elements of the presently claimed invention.
13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that

these statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____ April 24, 2006 _____

_____/Dr. Edward Coleman/_____
Dr. Edward Coleman

Docket No.: 021587-9001-02
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Exhibit A



CURRICULUM VITAE

NAME EDWARD J. COLEMAN, MD

BORN MAY 15, 1954

MARITAL STATUS MARRIED, 6 CHILDREN

EDUCATION

St. Augustine School Larchmont, New York	1968
Mamaroneck High School Mamaroneck, New York	1972
Norwich University Northfield, Vermont Degree: BA	1976
State University of New York at Buffalo School of Medicine Buffalo, New York Degree: M.D.	1981-1983

MILITARY

Lieutenant Commander, United States Navy Reserve Medical Corps	Commissioned August, 1987
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RESIDENCY

University of Rochester School of Medicine & Dentistry Internship & Resident Surgery (1984)	1983-1986
Columbia University College of Physicians & Surgeons Senior & Chief Resident	1986-1988
State University of New York at Buffalo Buffalo, New York Resident in Cardiothoracic Surgery	1988-1990

ACADEMIC APPOINTMENTS

University of Rochester School of Medicine Clinical Instructor in Surgery	1983-1986
Columbia University College of Physicians & Surgeons Mary Imogene Basset Hospital Cooperstown, New York Visiting Clinical Fellow in Surgery	1986-1988
State University of New York at Buffalo School of Medicine Clinical Instructor in Surgery	1988-1990

AWARDS

Alpha Omega Alpha	1983
State University of New York at Buffalo, School of Medicine	
1. Dean's Honor Commendation for Academic Excellence	1982
2. Merit Scholarship Award for Outstanding Academic Achievement	1983
3. Thesis Honors	1983
Buffalo Surgical Society Prize	1983
Recognition by University of Rochester Graduating Medical School Students as Outstanding Resident and Teacher of Medicine	1986
Medical Society State of New York, Merit H. Cash Award	1989
Siegel Teaching Award, State University of New York at Buffalo School of Medicine	1989
John H. Powers Memorial Prize	1989
Wisconsin Medical Society Meritorious Service Award Council on Health Care Access and Financing	2002

PRESENTATIONS

American College of Surgeons Upstate New York Chapter, Albany, New York	1988
Lecturer in Thoracic Anatomy University of Buffalo, School of Medicine	1988
Sternal Wound Infection - Update Nursing Inservice, Bellin Memorial Hospital	1991
Fluid and Electrolytes - Update Association of Critical Care Nurses of Northeast Wisconsin	1991
Endocarditis: Epidemiology, Pathogenesis, Prevention & Therapy Bellin Hospital, Green Bay, WI	1992
Thoracic Trauma Association of Critical Care Nurses of Northeast Wisconsin	1993
Coronary Artery Disease American Heart Association Dickinson County, Michigan	1994
Thoracoscopy Association of Critical Care Nurses of Northeast Wisconsin	1994
Coronary Artery Disease Door County, Wisconsin	1994
Thoracic Radiography WI Society of Radiology Technologists	1996
Thoracic Trauma Association of Critical Care Nurses of Northeast Wisconsin	1997
St. Vincent Regional Cancer Center Symposium Lung Cancer Update	2003
Blood Conservation St. Vincent Hospital, Green Bay, WI	2003

PRESENTATIONS
(Continued)

What's New in Thoracic and Cardiovascular Surgery Retired Men's Club	2003
Anticoagulation Update Bellin Health Family Medical Center	2004
The Cardiac Program in the 3rd Millennium St. Vincent and St. Mary's Hospitals	2004
Medical Education in the United States Catholic Medical Association, Philadelphia, PA	2004
Anticoagulation in Rehab & Long-Term Care Settings Bellin Hospital	2004
Venous Thromboembolism Update: ACCP Guidelines St. Vincent Hospital	2005
Home INR Monitoring New Horizons in Cardiac Care Symposium Genesys Regional Medical Center	02/11/2006

PUBLICATIONS

Small Bowel Injuries in Blunt Abdominal Trauma
Early Recognition and Management, E.J. Coleman, M.D.
P.A. Dietz, New York State Journal of Medicine
Vol. 90, No. 9, 446-450, 1990
Small Bowel Injuries in Blunt Trauma, E.J. Coleman, M.D.
P.A. Dietz, Yearbook of Emergency Medicine, 1991

LICENSURE/INVESTIGATOR

New York State, Medical License # 159466-1
FDA-DEA, License # AC2803129
Wisconsin State, Medical License # 31207
National Cancer Institute Investigator 22181
Eastern Cooperative Oncology Group, Investigator
American College of Surgeons Oncology Group #5895

CERTIFICATIONS

Diplomate, National Board of Medical Examiners
American Board of Surgery - Valid thru 07/01/2010
American Board of Thoracic Surgery - Valid thru 2011
North American Society of Pacing and Electrophysiology
Examination of Special Competency, Testamur 1996
Worker's Compensation
Advanced Cardiac Life Support
Advanced Trauma Life Support
Basic Life Support

SOCIETIES

American Medical Association
American College of Chest Physicians, Fellow - Wisconsin Governor 2003-2007
American College of Cardiology, Fellow
American College of Surgeons, Fellow
Wisconsin District #4 Committee of Applicants 1996-present
Society of Thoracic Surgeons
Medical Society of the State of New York
Erie County Medical Society
Founder, History of Medicine Society,
Mary Imogene Bassett Hospital
Brown County Medical Society - President 2004 - 2005
Wisconsin Medical Society
Wisconsin Medical Society Health Care Finance Committee, 1992 - 2002
American Heart Association, Fellow
Council on Cardiothoracic and Vascular Surgery
Wisconsin Medical Society
Council on Ethics and Judicial Affairs 2001 - 2004
Heart Rhythm Society 2003
American Thoracic Society 2004
Catholic Medical Association

HOSPITAL APPOINTMENTS

Attending Physician, Bellin Memorial Hospital	1990 - present
Attending Physician, St. Vincent Hospital	1990 - present
Attending Physician, St. Mary's Hospital	2001 - present
Attending Physician, Door County Memorial Hospital	2003 - present
Institutional Review Board, St. Vincent Hospital	1991-1994
Ethics Committee, Bellin Memorial Hospital	1994-1998
Cardiovascular Committee, Bellin Memorial Hospital	1990-present
Secretary, Medical Staff, Bellin Memorial Hospital	1991-1994
Investigator, National Cancer Institute	
Investigator, Eastern Cooperative Oncology Group	
Cardiac Medicine & Surgery Committee Chairman	1/1/02-12/31/03
Bellin Medical Executive Committee	2002-2004
Pharmacy and Therapeutics Committee, St. Vincent Hosp.	2003-2005